and along their and practice and a state of the state of JC20 Rec'd PCT/PTO 2 5 JAN 2902 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO 1390 (REV. 12-29-99) ATTORNEY'S DOCKET NUMBER DHN/322/PC/US TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (If known, see 37 CFR 1.5) CONCERNING A FILING UNDER 35 U.S.C. 371 10/069081 INTERNATIONAL FILING DATE INTERNATIONAL APPLICATION NO. PRIORITY DATE CLAIMED PCT/EP00/07204 July 26, 2000 July 27, 1999 TITLE OF INVENTION Orthopedic Bone Cement Mixing Container APPLICANT(S) FOR DO/EO/US David Foster, Anthony Jones and Rebecca Eveleigh Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay 3. examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed 4. priority date. A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is transmitted herewith (required only if not transmitted by the International Bureau). has been transmitted by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US) A translation of the International Application into English (35 U.S.C. 371(c)(2)). 6. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are transmitted herewith (required only if not transmitted by the International Bureau have been transmitted by the International Bureau. b. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 8. An oath or Declaration of the Inventor(s) (35 U.S.C. 371(c)(4)). (Unexecuted 9. A translation of the annexes to the International Preliminary Examination Report under PCT Article 10. 371(c)(5)). Items 11 to 16 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 11. An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 12. A FIRST Preliminary Amendment. 13. A SECOND or SUBSEQUENT Preliminary Amendment. 14 A substitute specification. 15. A change of Power of Attorney and/or address letter. Other items or information: 16.

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I, <u>Talisha L Cooper</u> , hereby certify that this paper or fee is being deposited with the United States Bestal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on <u>January 25, 2002</u> and us addressed to Box PCT, objuritssioner for Patents, Washington, DC 20231 "

Talisha L. Gooper

U.S. APPLICATION NO. (if	known, see 37CFR 1 5)	INTERNATIONAL APPLIC	ATION NO	ATTORNEY'S DOCKET NUMBER	BER
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Guy D. N	Yale, Esq.			(Guy D. Yale)	
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750 Maii	e & Ristas, LLP n Street, Suite 1400			29,125	
Hartford	, Connecticut 06103		REGISTRATION N	UMBER	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of David Foster, et al

Serial No.:

International

PCT/EP00/07204

Application No.:

Filing Date:

International

July 26, 2000

Filing Date:

For: Orthopedic Bone Cement Mixing Container

Commissioner for Patents Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Before calculating the filing fee and examining the application, please enter the following amendments:

The amendments are made with reference to the PCT application as officially published on July 26, 2000 as International Publication Number WO 01/06963 A2.

In the Specification:

After the title, insert —This application is the U.S. National Phase of International Application No. PCT/EP00/07204, filed on July 26, 2000.

BACKGROUND OF THE INVENTION-

Page 4, after line 22, insert —SUMMARY OF THE INVENTION—

Page 6, after line 7, insert —BRIEF DESCRIPTION OF THE DRAWINGS—

Page 6, after line 17, insert —DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS—

In the claims:

Please amend claims 4 through 9 as follows:

- 4. (amended) An apparatus as claimed in claim 2 [or 3], wherein the inner housing is attached to the cap by means of a snap fit arrangement.
- 5. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.
- 6. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said inner housing is less rigid than said outer housing.
- 7. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 8. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 9. (amended) An apparatus as claimed in [any preceding] claim 1, further comprising means allowing gas to circulate around the cement contained in the inner housing.

Please add new claims 11 through 20 as follows:

11. An apparatus as claimed in claim 3, wherein the inner housing is attached to the cap by means of a snap fit engagement.

- 12. An apparatus as claimed in claim 2, wherein said inner housing is provided with a feather tip seal for sealing against said housing.
- 13. An apparatus as claimed in claim 2, wherein said inner housing is less rigid than said outer housing.
- 14. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 15. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 16. An apparatus as claimed in claim 2, further comprising means allowing gas to circulate around the cement contained in the inner housing.
- 17. An apparatus as claimed in claim 3, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.
- 18. An apparatus as claimed in claim 3, wherein said inner housing is less rigid than said outer housing.
- 19. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 20. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

A CLEAN COPY OF THE AMENDED AND NEWLY ADDED CLAIMS IS ENCLOSED.

In the Abstract:

Please enter the Abstract of the Disclosure on the separate sheet enclosed herewith.

REMARKS

Applicant has amended the application to conform same to U.S. patent practice. Multiple dependent claims have been eliminated. An Abstract of the Disclosure on a separate sheet has been enclosed.

Applicant respectfully requests that the amendments be entered prior to calculation of the filing fee and examination of the application.

Respectfully Submitted,

David Foster, et al

BA:

Guy D. Yale Registration No. 29,125

Alix, Yale & Ristas, LLP Attorney for Applicant

Date: January 25, 2002 750 Main Street Hartford, CT 06103-2721 (860) 527-9211

Our Ref: DHN/322/PC/US

GDY/tlc

CLEAN COPY OF AMENDED CLAIMS

- 4. An apparatus as claimed in claim 2, wherein the inner housing is attached to the cap by means of a snap fit arrangement.
- 5. An apparatus as claimed in claim 1, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.
- 6. An apparatus as claimed in claim 1, wherein said inner housing is less rigid than said outer housing.
- 7. An apparatus as claimed in claim 1, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 8. An apparatus as claimed in claim 1, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 9. An apparatus as claimed in claim 1, further comprising means allowing gas to circulate around the cement contained in the inner housing.

- 11. An apparatus as claimed in claim 3, wherein the inner housing is attached to the cap by means of a snap fit engagement.
- 12. An apparatus as claimed in claim 2, wherein said inner housing is provided with a feather tip seal for sealing against said housing.
- 13. An apparatus as claimed in claim 2, wherein said inner housing is less rigid than said outer housing.
- 14. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 15. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 16. An apparatus as claimed in claim 2, further comprising means allowing gas to circulate around the cement contained in the inner housing.
- 17. An apparatus as claimed in claim 3, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.

- 18. An apparatus as claimed in claim 3, wherein said inner housing is less rigid than said outer housing.
- 19. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
- 20. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

ABSTRACT OF THE DISCLOSURE

The invention discloses a pre-filled orthopedic cement container in which the cement can also be mixed. The container comprises an outer housing defining the mixing chamber and an inner housing containing the cement prior to mixing. The inner housing is removable, prior to mixing, in such a way that the cement powder remains in the mixing chamber for mixing.

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Orthopaedic Bone Cement Mixing Container

This invention relates to a container in which orthopaedic bone cement is mixed.

Orthopaedic bone cement is used throughout the world to secure hip, knee and other metallic protheses in an appropriate anatomical position.

Many different systems are available for mixing orthopaedic bone cement and the type of apparatus selected will depend on the personal preferences of the doctor or nurse mixing the cement, as well as the amount of cement being mixed and the type of materials being used.

Essentially, orthopaedic cement is made up of a powder component, e.g. polymethylmethacrylate powder, and a monomer, eg.g. methylmethacrylate monomer liquid, generally provided in an ampoule which is broken and added to the powder. The two components are then thoroughly mixed to provide a malleable cement which can be manipulated and applied to the appropriate bone parts, during surgery.

In order to avoid the cement becoming brittle, it is essential that the two components are very thoroughly mixed together and no 'dry' or 'dead' spots remain. Furthermore, as most cements set fairly quickly, it is important that the mixing can be quickly and easily carried out. This is, also, of course important as surgery should be carried out as quickly as possible for the comfort and safety of the patient.

Originally, the cement components were mixed, by hand, using a bowl and spatula. A theatre nurse would mix the appropriate quantities of the two components in the bowl and the physician would then take some of the mixed cement and mould it to the required shape, before inserting it into a preformed cavity or applying it to a resected bony surface where the prothesis is to be

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positioned. Cement may either be applied by hand or may be put into a syringe and applied thereby.

Although mixing in this way is straightforward and convenient, it can have drawbacks.

from the mixture. It is desirable to remove these fumes, or prevent them from escaping into the atmosphere, since they have an unpleasant odour and may be harmful to operating room and personnel. The fumes are known to cause nausea and giddiness and are generally objectionable, particularly to the nurses who actually carry out the mixing.

Secondly, a very high mixing efficiency is required to produce a homogenous cement material During the mixing process, air is naturally introduced into the mixture since air is inherently existent within the powder and also in and around the mixing vessel. Air bubbles are also produced by the 'boiling off' of monomer which occurs during the mixing process. The introduction of air produces a weak cement and, since the joint must usually support a heavy load, it is important to reduce the amount of air in the mixture as much as possible in order to improve the mechanical strength of the cement material.

result in the cement beginning to dry out before it has been used and can require the patient to be on the operating table longer than desirable. Where particularly viscous cements are used, mixing in this way can also be rather tiring for the theatre nurse and can, in some cases, lead to muscle fatigue and strain.

A variety of systems is now available to simplify and improve the mixing of bone cement and to overcome the problems mentioned above. Many of these include the application of a vacuum to a sealed mixing chamber which removes air from the mixture and avoids weak spots. This results in a greatly improved cement.

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One such mixing device is the bowl mixer forming the subject of European Patent No. 0616552. This system is preferred by many users as it is small and convenient to use and the mixing action is similar to that carried out in the above described manual bowl mixing technique and is one with which nurses are generally familiar.

Patent No. 0744991. In this arrangement, the cement is mixed in a cylindrical mixing chamber. The mixing mechanism comprises paddles rotatably mounted within the chamber. The paddles are rotated around the chamber by means of a 'barley twist' mechanism so that the user merely has to push the handle up and down, to cause rotation of the paddle. Furthermore, once the cement is mixed, this system can be converted into a syringe type dispenser by addition of a nozzle and plunger. There is thus no need to remove the mixed cement from the mixing chamber and transfer it to a dispenser.

Other similar mixing arrangements are known.

In all of these systems, the cement components need to be put into the mixing chamber. Generally, the nurse is provided with the cement powder, in a bag, and monomer ampoule. These are opened by the nurse, manually, and are introduced into the mixing chamber or bowl by means of funnels.

One problem is that when cutting open the cement powder bag and inserting the powder via the funnel, there is a certain degree of wastage due to spillage and cement clinging to the funnel. Furthermore, the opening and pouring of the cement powder caused a powder cloud which, within the regulated confines of the operating theatre, is unpleasant and may even have adverse effects on the theatre personnel.

These problems become more acute when time is very short and the mixing must be done extremely quickly, or with inexperienced theatre personnel.

One solution which has been considered is to

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provide a pre-filled mixing apparatus, wherein the disposable mixer, for example a bowl mixer or syringe mixer as described above, is supplied already containing the cement powder in the mixing chamber. This generally makes things much easier for the theatre nurse when needing to mix the cement quickly during an operation.

However, tests have shown that if the cement powder is housed within the mixing chamber or bowl and contained therein by means of a cap, the powder moves about, particularly during transportation, and covers the entire internal surface area of the mixing chamber and the lid. When the mixing is carried out, with the introduction of the monomer, unmixed powder remains at the top of the mixing vessel due to the monomer not wetting all of the walled surface, and the mixing paddle not reaching the very fine layer of powder on the walls and at the top of the chamber. Thus, powder is wasted and 'dry' spots occur, resulting in brittle cement which can have adverse consequences.

The aim of the present invention is to provide a pre-filled orthopaedic cement mixing apparatus in which the above mentioned problems are overcome.

, According to one aspect of the present invention, there is provided an apparatus for containing and mixing orthopaedic cement, the apparatus containing an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, wherein the inner housing is removable from the outer housing such that the cement remains in the mixing chamber.

In accordance with another aspect of the invention, there is provided a method of providing and mixing of orthopaedic cement comprising sealing said cement in an inner housing; disposing said inner housing within an outer housing which defines a mixing chamber; removing the inner housing, leaving the cement in the mixing chamber for mixing.

The present invention may be incorporated into any

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known cement mixing arrangements including the bowl mixer and syringe mixer described above. It may also be incorporated in mixing bowls where the mixing is carried out simply using a spatula etc.

The inner housing may be removable from the outer housing in any way, for example it may be in the form of a bag which is merely lifted out by the user, which opens on removal to drop the cement powder into the mixing chamber. In the most preferred embodiment, however, the inner housing is attached to or formed integrally with a lid provided on the container. The inner housing and the lid may, for example, be attached to each other by a snap fit arrangement or, indeed, by any other means of attachment. Thus, when the cement is to be mixed, the lid is removed by the user and as the lid is removed, it takes with it the inner housing.

To provide a secure container during transportation etc., the lid is preferably attached to the outer housing by means of a screw thread. Seals may also be provided.

The inner housing may be made of any materials suitable for containing the cement powder. Preferably, the material of which the inner housing is made is less rigid than that of the outer housing. This allows the inner housing to be compressed against the outer housing to provide a good seal at the open end of the inner housing.

It is important that, prior to removal of the inner housing, the cement is securely contained within the housing and, therefore, the 'open' end of the inner housing should form a seal with the outer housing or should be closed after filling.

Thus, in one embodiment, not shown, the inner housing has an open end into which the cement is inserted. This open end is then closed by any suitable means and the inner housing is placed within the outer housing in such a manner that when the inner housing is

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removed from the outer housing, the inner housing is opened or ruptured allowing the cement to fall out into the inner housing.

In the most preferred arrangement, the inner housing, at the open end, is provided with a feather seal edge which provides a seal against the base or lower part of the outer housing.

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings.

Fig. 1 shows a cross-section of a mixing system according to the present invention.

Figs. 2A-2D show the different stages of inserting and mixing the cement using the apparatus shown in Fig. 1.

Fig. 3 shows an alternative embodiment of the present invention.

The embodiment shown in Fig. 1 uses a mixing system such as described in EP 0744991. This comprises a cylindrical mixing chamber, in which is arranged a mixing paddle (not shown), rotated by means of a handle connected thereto by a 'barley twist' rod and gear mechanism. The paddle is rotated around the mixing chamber by a pushing and pulling action on the handle. Vacuum is applied to the chamber during the mixing. Once the cement is mixed, the cap and mixing mechanism are removed and replaced by a nozzle. A plunger is applied to the other end of the mixing chamber and is pushed through the chamber, by means of, e. g., a mastic-type gun to eject the mixed cement through the

nozzle.

This mixing system is modified by the present invention and is provided as a pre-filled system.

Thus, the cement is provided in an inner housing 2 which is located in the outer, mixing chamber housing 3.

The inner housing, containing the cement 4, is attached to the cap 5 of the mixing chamber by a snap

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fit arrangement 6. This creates a seal through which the cement powder cannot pass.

Fig. 2A shows how the cement is inserted into the inner housing, via the open end 7 of the housing.

The outer housing 3 incorporating the piston and base 8 is then fitted over the cement containing inner housing as shown in Fig. 2D.

Guide lips 9 may be provided on the outer surface of the inner housing to assist in the correct positioning of the outer housing relative to the inner housing.

The outer housing is then secured to the cap, by means of a screw thread 10, as shown in Fig. 2C. The open end of the inner housing, containing the cement, is provided with a seal 11, preferably a feather seal, which fully seals to the piston part of the outer housing to secure the cement powder within the inner housing. This results in a fully sealed packaged container, containing the cement powder within the inner housing, ready for use. The whole device is then packaged and sterilised for use.

A breather pad (not shown) may be provided on the cap so as to allow gas circulation to the cement.

As shown in Fig. 2D, when the cement is to be mixed, the user unscrews the cap 5 from the outer housing 2 and lifts away the cap and the inner housing 3 connected thereto. As the inner housing is lifted away from the base of the outer housing, the cement powder 4 drops out of the inner housing into the mixing chamber 1. The cap and inner housing are then discarded and the standard mixing procedure for this type of mixing arrangement is carried out.

A similar procedure is used in relation to other mixing arrangements such as the bowl mixer 12 shown in Fig. 3. This may be a bowl as described in EP 0616552. The principle is essentially the same. An inner housing 3', containing the cement powder 4', is attached to the

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lid 5' of the bowl at one end and is sealed 11' to the base of the bowl or the sides of the bowl near its base by means of e. g. a feather seal. In use, the lid 5' and attached inner housing 3' are removed, such that the cement powder 4' drops out of the inner housing into the mixing chamber 1' and mixing is carried out in the usual way.

It is preferable that the inner housing is made of a material which is less rigid than the outer housing. This allows the feather seal edge of the inner housing to be compressed unto the outer housing to provide a secure seal for the cement powder.

In the preferred syringe type arrangement, the inner housing is designed to hold up to 80g of cement powder, i. e. a double mix of cement. In the case of the bowl mixer, preferably, the inner housing can hold up to 120g, i. e. a triple mix of cement.

Because the cement powder is contained within the inner housing until it is to be mixed, and is then dropped out of the housing only into the bottom of the mixing chamber, no cement clings to the upper outer walls of the mixing chamber and so practically all of the cement can be thoroughly mixed, producing a high quality mixed orthopsedic cement.

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CLAIMS

- 1. An apparatus for containing and mixing orthopaedic cement, the apparatus containing an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, wherein the inner housing is removable from the outer housing such that the cement remains in the mixing chamber.
- 2. An apparatus as claimed in claim 1 wherein the outer housing is provided with a cap and wherein the inner housing is attached to said cap such that the cap and inner housing can be removed from the outer housing together.
- 3. An apparatus as claimed in claim 2 wherein the cap is attached to the outer housing by means of a screw thread.
 - 4. An apparatus as claimed in claim 2 or 3 wherein the inner housing is attached to the cap by means of a snap fit arrangement.
 - 5. An apparatus as claimed in any preceding claim, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.
 - 6. An apparatus as claimed in any preceding claim wherein said inner housing is less rigid than said outer housing.
 - 7. An apparatus as claimed in any preceding claim wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.
 - 8. An apparatus as claimed in any preceding claim

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wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

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9. An apparatus as claimed in any preceding claim, further comprising means allowing gas to circulate around the cement contained in the inner housing.

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10. A method of providing and mixing of orthopaedic cement comprising sealing said cement in an inner housing; disposing said inner housing within an outer housing which defines a mixing chamber; removing the inner housing, leaving the cement in the mixing chamber for mixing.

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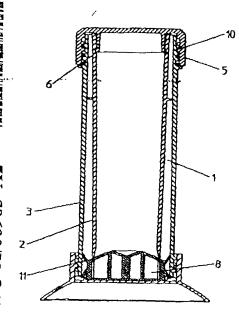
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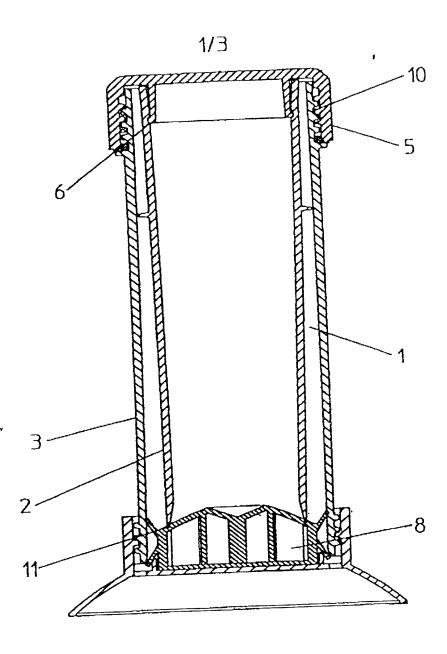
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) THIC: ORTHOPAEDIC BONE CEMENT MIXING CONTAINER

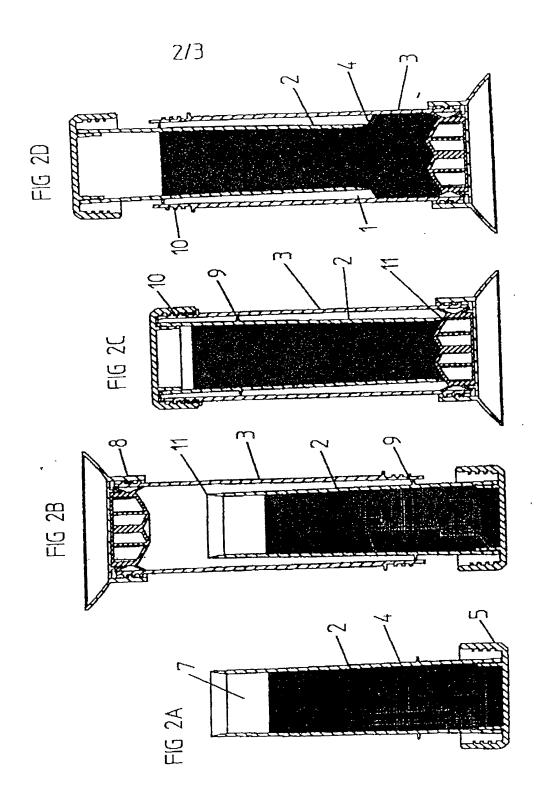


(57) Abstract: The invention discloses a pre-filled orthopsedic cement container in which the cement can also be mixed. The container comprises an outer housing defining the mixing chamber and an inner housing containing the coment prior to mixing. The inner housing is removable, prior to mixing, in such a way that the coment powder remains in the mixing chamber, for

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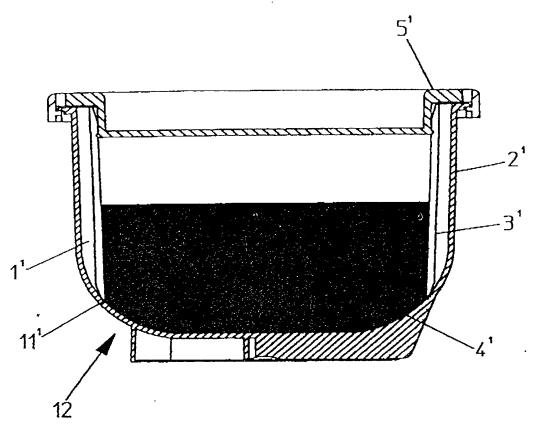


FIG 3

Attorney Docket DHN/322/PC/US 0010/PTO U.S. Department of Commerce First Named Inventor David Foster, et al Rev. 6/95 Patent and Trademark Office COMPLETE IF KNOWN **DECLARATION Application Number** Filing Date Declaration Submitted Declaration Submitted with Initial Filing after Initial Filing Group Art Unit **Examiner Name** As an above named inventor, I hereby declare that: My residence, post office address, and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: Orthopedic Bone Cement Mixing Container (Title of the Invention) the specification of which is attached hereto OR was filed on (MM/DD/YYYY) July 26, 2000 as United States Application or PCT International Application Number PCT/EP00/07204 _____ (ıf applicable). and was amended on (MM/DD/YYYY) I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above. l acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Codes of Federal Regulations, §1.56. I hereby claim foreign priority under Title 35, United States Code § 119 (a)-(d) or § 365 (b) of any foreign application(s) for patent or inventor's certificate, or § 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed. Prior Foreign Foreign Filing Date Copy Attached Country **Priority Not Claimed Application Numbers** (MM/DD/YYYY) Yes No 9917624.0 United Kingdom July 27, 1999 X Additional foreign application numbers are listed on a supplemental priority sheet attached hereto: I hereby claim the benefit under Title 35, United States Code § 119 (e) of any United States provisional application(s) listed below: Filing Date Application Number(s) (MM/DD/YY) Additional provisional application numbers are listed on supplemental priority sheet attached hereto.

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		Dr	<u></u>	RATIO	<u> </u>										Page 2
I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Title Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application. U.S. Parent Application PCT Parent Number Parent Filing Date Parent Patent Number															
U.S. Pa	arent Ap Numbe		PC	CT Parent I	Number					ing Date Parent Patent Number (if applicable)					
Additional U.S. or PCT International application numbers are listed on a supplementary priority sheet attached hereto: As a named inventor, I hereby appoint the registered practitioners associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office therewith, and direct that all correspondence be addressed to that Customer Number:															
<i>;</i>	Firm Nan	ne:	Alix,	, Yale & Ri	stas, LLI	Р		Custom	ner Nur	mber:	[0025	43	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.															
Name of	Sole or	r First Inve	entor					A petiti	ion has	s been	filed for this	s unsiç	gned inv	ento	ır
Given Name		David		Middle Initial		Fami Nam			Fos	ster	;	Sur	ffix		
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Name of	Addition	nal Joint Ir	nventor, if	any:				A petiti	ion has	s been	filed for this	s unsig	gned inv	ento	Pr .
Given Name		Anthony	y	Middle Initial		Fami Nam	,		Jon	ies		Suf	fix		
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DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet

Name of	Name of Additional Joint Inventor, if any:									A petition has been filed for this unsigned inventor						
Given Name		Rebecca		Middle Initial		amily Name	Eveleigh					Suffix				
Invent Signat								Date								
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Add	litional i	nventors ar	e being	named on	supplement	tal sheet	(s) a	ttached	here	to						

inside this box \rightarrow [+] DHN/322/PC/US **Attorney Docket** U.S. Department of Commerce 0010/PTO First Named Inventor David Foster, et al Rev. 6/95 Patent and Trademark Office COMPLÉTE IF KNOWN DECLARATION Application Number Filing Date Declaration Submitted Declaration Submitted after Initial Filing with Initial Filing Group Art Unit **Examiner Name** As an above named inventor, I hereby declare that: My residence, post office address, and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: Orthopedic Bone Cement Mixing Container (Title of the Invention) the specification of which is attached hereto OR was filed on (MM/DD/YYYY) July 26, 2000 as United States Application or PCT if pplication Number PCT/EP00/07204 and was amended on (MM/DD/YYYY) _ (if applicable). ecification, including the claims, as amended by I hereby state that I have reviewed and understood the contents of the above-iden any amendment specifically referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Codes of Federal Regulations, §1.56. I hereby claim foreign priority under Title 35, United States Code § 119 (a)-(d) or § 365 (b) of any foreign application(s) for patent or inventor's certificate, or § 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed. Copy Attached Foreign Filing Date Prior Foreign **Priority Not Claimed** Country Yes No (MM/DD/YYYY) **Application Numbers** 図 July 27, 1999 **United Kingdom** 9917624.0 Additional foreign application numbers are listed on a supplemental priority sheet attached hereto: I hereby claim the benefit under Title 35, United States Code § 119 (e) of any United States provisional application(s) listed below: Filing Date Application Number(s) (MM/DD/YY) Additional provisional application numbers are listed supplemental sheet priority attached hereto.

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application design	naung the On the prior U 2, I acknow ons §1.56 wh	latted St	ates or PC	T Internat	ional app	dication in t	ie mannei	provided by	ule ilist parag	f any PCT International laims of this application raph of Title 35, United Title 37, Title Code of PCT International filing			
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Additional U.	S, or PCT in	tematio	nal applica	tion numbe	ers are lis	sted on a su	plementa	ry priority she	et attached he	ereto:			
As a named investigation and it that Customer N	entor, I herel to transact a umber:	by appoi	nt the regi	stered pra Patent and tas, LLP	cuioners i Tradem	ark Office t	with the C nerewith, a r Number:	and direct tha	t all correspon	ndence be addressed to.			
I hereby declare believed to be to punishable by fi may jeopardize	ne: and inin	let nier	a look and	dar Saction	n 1001 o	f Title 18 of thereon.	the United	States Code	estatements a and that suc	nformation and belief are and the like so made are h willful false statements entor			
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Given Name	David,		Middle Initial		Family Name		F <u>oster</u>		Suffix	/ /			
Inventor's Signature			B			r		Date	X 20	9/6/02			
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Given Name	Anthony	-	Middle Initial		Family Name		Jones		Suffix				
Inventor's Signature	X	20	Ha	W.				Date	× 5/	7102			
RESIDENCE:	Abing	don	State	Охо	on	Country	United	Kingdom	Citizenship	United Kingdom			
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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet

Name of Additional Joint Inventor, if any:									A petition has been filed for this unsigned inventor							
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City	Che	ltenham	State				Zip GL51 6ND Country Kingo									
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Addi	Additional inventors are being named on supplemental sheet(s) attached hereto															